

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 25.05.2023

Date of compilation: 25.05.2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

- **Trade name:** PT-141 Bremelanotide
- **Chemical Identification:** PT-141 Bremelanotide
- **Other chemical names** Ac-Nle-cyclo[Asp-His-D-Phe-Arg-Trp-Lys]-OH
- **CAS Number:**
189691-06-3
- **EINECS Number:** -
- **Index number:** -
- **Registration number**
Registration number for this substance has not yet been assigned or the substance is manufactured / imported in a volume that does not require its registration.

1.2 Relevant identified uses of the substance or mixture and uses advised against

- **Sector of Use** SU24 Scientific research and development
- **Application of the substance / mixture**
Raw material for research and development.
(see more labels, or product / data sheet)
- **Not recommended uses** All except above mentioned uses.

1.3 Details of the supplier of the safety data sheet

- **Manufacturer/Supplier:**
PARTICLE s.r.o.
Kolonáda 4490/18
SK-984 01 Lučenec (Slovakia)
Tel: +421 917 149 682
E-mail: info@particlepeptides.com
- **Further information obtainable from:** EKO-ADR, s.r.o., ekoadr@ekoadr.sk

1.4 Emergency telephone number:

Poisons Centres in Europe (consultation in case of acute intoxication):
<http://www.eapcct.org/index.php?page=links>

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

- **Classification according to Regulation (EC) No 1272/2008**
The substance is not classified, according to the CLP regulation.
- **Additional information:**
Although the product is not classified as dangerous, may show signs of danger (see sections 9-12 SDS).

2.2 Label elements

- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Precautionary statements** Void
- **Additional information:**
EUH210 Safety data sheet available on request.

2.3 Other hazards

- **Results of PBT and vPvB assessment**
- **PBT:**
According to the information available, the product does not meet criteria such as PBT - persistent, bioaccumulative and toxic (substance on its own or in a mixture with concentration $\geq 0.1\%$ by weight).
- **vPvB:**
According to the information available, the product does not meet criteria such as vPvB - very persistent, very bioaccumulative (substance on its own or in a mixture with concentration $\geq 0.1\%$ by weight).
- **Determination of endocrine-disrupting properties**
According to the information available, the product does not meet the criteria for having endocrine disrupting properties (substance on its own or in a mixture with concentration $\geq 0.1\%$ by weight).

SECTION 3: Composition/information on ingredients

3.1 Substances

- **CAS No. Description**
CAS: 189691-06-3, PT-141 Bremelanotide

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· **Additional information:** Sequence: Ac-Nle-cyclo[Asp-His-D-Phe-Arg-Trp-Lys]-OH

SECTION 4: First aid measures

· 4.1 Description of first aid measures

· **General information:**

Remove contaminated clothing and shoes (use of personal protective equipment, see section 8). In case of any uncertainty or if any symptoms occur, seek medical assistance and show this SDS or label. Protect your health. Information for doctor: treatment is symptomatic.

· **After inhalation:** Ensure of fresh air. In the event of symptoms refer for medical treatment.

· **After skin contact:**

In case of contact with skin wash off with soap and water. Remove contaminated clothing. Seek medical help if necessary.

· **After eye contact:**

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical help if necessary.

· **After swallowing:**

If swallowed by mistake wash out with plenty of water. Do not induce vomiting. Call doctor immediately.

· 4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available (for more see sections 2 and 11).

· 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

· 5.1 Extinguishing media

· **Suitable extinguishing agents:**

Carbon dioxide, dry extinguisher, alcohol resistant foam (large fire). Cool container at risk with water jet spray. Fire-extinguishing activities according to surrounding.

· **For safety reasons unsuitable extinguishing agents:** Not determined.

· 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

Carbon dioxide (CO₂).

Carbon monoxide (CO).

Nitrogen oxides (NO_x)

Ammonia (NH₃).

Cyanide oxides (CNO_x).

Sulphur oxides (SO_x).

· 5.3 Advice for firefighters

· **Protective equipment:**

Do not stay in dangerous zone without self-contained breathing apparatus. Use chemical overall and equipment.

· **Additional information**

Cool container with spray water from a safe distance. Contain escaping vapours with water. Prevent fire-fighting water from entering surface water or groundwater.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel:

Do not inhale dust. Ensure supply of fresh air in enclosed rooms. Avoid contact with eyes and skin.

6.1.2. For emergency responders:

More info in section 5.

· **6.2 Environmental precautions:** Do not discharge into the drains/surface waters/groundwater.

· **6.3 Methods and material for containment and cleaning up:**

Spilled product mechanically collect and then place in suitable containers. Follow disposal is governed by regulations set out in section 13, watch the value in section 8. The affected area and used tools thoroughly wash with suitable detergent, do not use solvents.

· **6.4 Reference to other sections**

See section 7 for information on safe handling. See section 8 for information on personal protective equipment. See section 13 for information on safe disposal.

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SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Before the usage check out sections 2, 6, 8 and 11. Don't breathe aerosol/dust. Eating, drinking, smoking as well as food storage, is prohibited in work room.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Store in a dry place. Protect against water and moisture.
Store only in the original properly sealed and marked containers.
Store in accordance with the requirements stated on the label / in the technical specification from the manufacturer / supplier.
Store in closed containers at temperatures:
-18 ° C for 3 years
0 - 7 ° C for 1 year
7 - 30 ° C for half a year
- **Information about storage in one common storage facility:**
Store away from foodstuffs.
Do not store with incompatible materials (see section 10).
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** Right usage of product is enclosed in product documentation or on label.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
General maximum dust: 10 mg / m³ for respirable dust. See local regulations.
- **8.2 Exposure controls**
- **8.2.1 Appropriate engineering controls:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **8.2.2 Individual protection measures, such as personal protective equipment:**
- **Respiratory protection:**
 Normally not needed. In case of insufficient ventilation, the creation of dust and excess of permitted exposure limits use appropriate respiratory mask with filter against solid aerosols.
Filter P (EN 14387).
- **Skin protection / Hand protection**
 Protective gloves (EN 374).
- **Material of gloves**
Nitrile rubber, NBR (EN 374).
Recommended thickness of the material: ≥ 0.4 mm
- **Penetration time of glove material**
≥ 480 min (EN 16523-1).
Glove material must be impermeable and resistant against product / substance / preparation. Gloves material should comply with breakthrough times, permeation rates, and degradation. Requirements can vary as a function of the use. Therefore it is necessary to adhere additionally to the recommendations given by the manufacturer of protective gloves.
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye/face protection**
 Safety goggles (EN 166).

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· Skin protection / Other:



Protective clothing with long sleeves (EN ISO 6529) and safety shoes (EN ISO 20345, EN ISO 20346, or EN ISO 20347).

· Thermal hazards Void.

· 8.2.3 Environmental exposure controls

Close the packaging properly after and during the work. Store containers stably. Avoid tipping over unsecured packaging. Clean contaminated packaging from contaminant.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state:

Solid
Powder

· Colour:

White
or
Different according to colouring

· Odour:

No further relevant information available.

· Odour threshold:

Not determined.

· Melting point/freezing point:

Undetermined.

· Boiling point or initial boiling point and boiling range

Undetermined.

· Flammability

Product is not flammable.

· Lower and upper explosion limit

· Lower:

Not determined.

· Upper:

Not determined.

· Flash point:

Not applicable.

· Auto-ignition temperature:

Not determined.

· Decomposition temperature:

230 °C

· pH

Not applicable.

· Kinematic viscosity

Not applicable.

· Dynamic:

Not applicable.

· Solubility

· water:

Soluble.

· Partition coefficient n-octanol/water (log value)

Not determined.

· Vapour pressure:

Not applicable.

· Density and/or relative density

· Absolute density:

Not determined.

· Relative vapour density

Not applicable.

· Particle characteristics

Not determined.

· 9.2 Other information

· Explosive properties:

Product does not present an explosion hazard.

· VOC (EC)

Not determined.

· Change in condition

· Evaporation rate

Not applicable.

· Information with regard to physical hazard classes

· Explosives

Void

· Flammable gases

Void

· Aerosols

Void

· Oxidising gases

Void

· Gases under pressure

Void

· Flammable liquids

Void

· Flammable solids

Void

· Self-reactive substances and mixtures

Void

· Pyrophoric liquids

Void

· Pyrophoric solids

Void

· Self-heating substances and mixtures

Void

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- | | |
|--|------|
| · Substances and mixtures, which emit flammable gases in contact with water | Void |
| · Oxidising liquids | Void |
| · Oxidising solids | Void |
| · Organic peroxides | Void |
| · Corrosive to metals | Void |
| · Desensitised explosives | Void |

SECTION 10: Stability and reactivity

- **10.1 Reactivity** See section 10.3.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** See section 7.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** Strong oxidizing agents.
- **10.6 Hazardous decomposition products:** See section 5.

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
 - **Acute toxicity** Based on available data, the classification criteria are not met.
 - **LD/LC50 values relevant for classification:**
Caution! To the best of our knowledge the toxicological properties of this material have not been thoroughly investigated.
 - **Skin corrosion/irritation:**
Based on available data, the classification criteria are not met.
Longer contact may cause irritation of the skin and possibly dermatitis (skin inflammation). The product degreases and dries the skin.
 - **Serious eye damage/irritation:**
Based on available data, the classification criteria are not met.
The product may irritate the eyes.
 - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
 - **Carcinogenicity** Based on available data, the classification criteria are not met.
 - **Reproductive toxicity** Based on available data, the classification criteria are not met.
 - **Respiratory or skin sensitisation**
Based on available data, the classification criteria are not met.
Sensitisation possible through skin contact.
 - **STOT-single exposure:**
Based on available data, the classification criteria are not met.
Inhalation of dust can cause irritation of the respiratory tract.
 - **STOT-repeated exposure:** Based on available data, the classification criteria are not met.
 - **Aspiration hazard:** Based on available data, the classification criteria are not met.
-
- **Ingestion respons:**
Ingestion: abdominal discomfort and other negative effects (sickness, nausea etc.). The effects may be immediate, or even later.
 - **Mixtures / mixture versus substance information** Not applicable. It is a substance.
 - **Information on likely routes of exposure** See the above information in section 11.
 - **Symptoms related to the physical, chemical and toxicological characteristics**
See the above information in section 11.
 - **Delayed and immediate effects as well as chronic effects from short and long-term exposure**
See the above information in section 11.
 - **Interactive effects** No data available.
 - **Absence of specific data** No data available.
 - **11.2 Information on other hazards**
- | |
|--|
| · Endocrine disrupting properties |
| Substance is not listed. |
- **Other information** See the above information in section 11.

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SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:**
Caution! To the best of our knowledge the ecotoxicological properties of this material have not been thoroughly investigated.
- **12.2 Persistence and degradability (in water)** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
Not classified as hazardous for environment.
Do not allow product to reach ground water, water course or sewage system, even in small quantities.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Hand over the waste only to a person authorized for further waste disposal / processing according to the waste catalog. At compliance with all physico-chemical (and other) aspects of the nature of the waste respect the waste management hierarchy: 1. Prevention, 2. Reuse, 3. Material recovery (recycling), 4. Other uses (eg energy), 5. Disposal (eg landfilling - only for solid or stabilized liquid waste). See section 15 for waste disposal legislation.
- **European waste catalogue**
Catalogue numbers with an asterisk (*) indicate hazardous wastes (H), numbers without asterisk indicates non-hazardous waste (NH).

16 03 06	organic wastes other than those mentioned in 16 03 05
15 01 02	plastic packaging
20 01 39	plastics

- **Uncleaned packaging:**
- **Recommendation:** Dispose as a non hazardous waste.

SECTION 14: Transport information

· 14.1 UN number or ID number	
· ADR/RID/ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name	
· ADR/RID/ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· ADR/RID/ADN, IMDG, IATA	
· Class	Void
	-
· ADN/R Class:	Void
· 14.4 Packing group	
· ADR/RID/ADN, IMDG, IATA	Void
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	Not dangerous according to the above specifications.

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SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **REGULATION (EU) 2019/1148 on the marketing and use of explosives precursors**

- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

Substance is not listed.

- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

Substance is not listed.

- **Regulation (EC) No 273/2004 on drug precursors**

Substance is not listed.

- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

Substance is not listed.

- **European legislation:**

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP), amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (and subsequent amendments and supplements).

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (and subsequent amendments and supplements).

COMMISSION REGULATION (EU) No 2020/878 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties.

DIRECTIVE 2008/98/EC OF THE EP AND OF THE COUNCIL on waste and repealing certain Directives (and subsequent amendments and supplements).

- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Training hints** Workers must be trained in accordance with local provisions.

- **Abbreviations and acronyms:**

ADR: Accord sur le transport des marchandises dangereuses par Route (Agreement concerning the International Carriage of Dangerous Goods by Road)

ATE: acute toxicity estimate

CAS: Chemical Abstract Service

CLP – Classification, Labeling and Packaging of substances and mixtures (abbreviation for Regulation 2008/1278/EC)

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

EL50: : Effective Loading, 50 %

ErC50 / EC50: value of the effective concentration of the test substance at which 50% of the test organisms die or immobilize

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

IATA: International Air Transport Association

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

IMDG: International Maritime Code for Dangerous Goods

LC50: lethal concentration that causes death in 50% of the test population

LD50: lethal dose that causes death in 50% of the test population (median lethal dose)

LL50: median lethal loading

NLP: No-Longer Polymers

NO(A)EL: dose value without observed adverse effect

NOEC: highest concentration of the substance at which no adverse effects are observed

NOELR: no-observable effect loading rate

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

SDS: Safety Data Sheet

UFI: unique formula identifier (code according related toxicological center can identify the dangerous properties of the substance / mixture from the label after poisoning)

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VOC: Volatile Organic Compounds (USA, EU), TOC: Total Organic Compounds
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

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